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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/09/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/673,795

Applicant(s)

TRIEBEL ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 January 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31, 34, 35, 37, 38 and 41-65 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 12, 16-18, 22-29, 37, 38 and 41-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-11, 13-15, 19-21, 30, 31, 34, 35, 64 and 65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \*   c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. The amendment filed 1/3/2003 (paper no. 16) is acknowledged and entered into the record. Accordingly, no claims have been canceled, claims 64 and 65 are newly added.
2. Claims 1-31, 34-35, 37-38, 41-65 are pending, claims 1-6, 12, 16-18, 22-29, 37-38, and 41-63 are withdrawn from further consideration as being drawn to a non-elected invention. Applicant is reminded to cancel all non-elected claims.
3. Therefore claims 7-11, 13-15, 19-21, 30-31, 34-35, and 64-65 are examined on the record.

#### ***Claim Rejections Withdrawn - 35 USC § 112, 2<sup>nd</sup> paragraph***

4. The rejection of claims 11 and 13 under 35 USC 112, 2<sup>nd</sup> paragraph is withdrawn in view of the amendments and arguments set forth by the applicant.
5. The rejection of claims 7-10, 13-14, 19-21, 30-31, and 34-35 under 35 USC 112, 2<sup>nd</sup> paragraph is withdrawn in view of the amendments set forth by the applicant.

#### ***Claim Rejections Maintained - 35 USC § 112, 1<sup>st</sup> paragraph***

6. The rejection of claims 11, 13-14, and 21, and now newly amended claims 7-10, 19-20, 30-31, and 64-65 under 35 USC 112, 1<sup>st</sup> paragraph as lacking proper written description, is maintained for the reasons of record. Applicant argues that the specification teaches that the one mutation or modification is at amino acid position 293 and that SEQ ID No: 1 and 2 are the preferred sequences that represent the one mutation or modification. Applicant further argues that the specification has taught amino acid sequences that are 80% homologous to naturally occurring hsp70.

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Applicant further argues that the structural and physical properties of the sequences are disclosed in the specification so as to notify one of skill that applicant were in possession of the invention at the time of filing. Applicant's arguments have been carefully considered but are not found persuasive. Although the specification does teach that at position 293 mutations or modification to the amino acid sequence include isoleucine, leucine, valine, alanine, glycine or phenylalanine, such limitations are not found in the claims and as such the claims read on any modification or mutation to the amino acid sequence. Furthermore, because the claims have not specifically pointed out to one of skill which mutation or modification is to take place, there is no way for one of skill to know which modification or mutation is actually being claimed. Furtherstill, sequences that are 80% homologous to naturally occurring hsp70 cannot be clearly and definitively determined, because numerous proteins may fall within this range. Also, there is no way for one of skill to determine to which part of the sequence the applicant intends to claims because the actual amino acid sequence which defines the 80% homology to naturally occurring hsp70 has not been defined or exemplified by the claims. Therefore, the specification has not adequately described peptides fragments with a mutation or modification nor has the specification adequately described peptide fragments that are 80% homologous to hsp70 because an amino acid sequence has not been taught.

***Claim Rejections Maintained - 35 USC § 112, 1<sup>st</sup> paragraph***

7. The rejection of claims 11, 34 and 35 under 35 USC 112, 1<sup>st</sup> paragraph as lacking an enabling disclosure is maintained for the reasons of record. Applicant argues

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that some experimentation is acceptable and further argues that the instant invention would only at best require routine experimentation because the number of sequence actually claimed is limited. Applicant's arguments have been carefully considered but are not found persuasive. Because the claims of the instant application claims sequences of which no amino acid has been associated, and because the claims recite functional limitations that require the elicitation of T-cell immune responses, one of skill in the art would be forced into large amounts of experimentation. The determination of peptides that have antigenic properties as disclosed by Gaiger *et al* (cited in the prior office action) is not considered routine because not all peptides are able to generate an effective or strong immune response. The specification has not taught whether the peptides claimed are effective in generating an immune response. The actual doses, time course, the half life, and bioavailability of the peptide have not been tested. Such factors are critical for peptides to be useful in the generation of any immune response. Because the specification has not taught any of these factors, and because the unpredictable nature of peptides in generating immune response, the specification has not enabled the instant invention.

***Claim Rejections Maintained - 35 USC § 102***

8. The rejection of claims 7-10,13,19,21,30,34, and 35 under 35 USC 102 (b) as being anticipated by Dragon *et al* is maintained for the reasons of record. Applicant argues that Dragon *et al* do not specifically teach the functional limitation of using hsp70 derived peptide in the elicitation of T-cell immune responses and further do not contemplate the use of hsp70 fragments. Applicant's arguments have been carefully

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considered but are not found persuasive. The claims of the instant invention are drawn to a peptide that comprises 8 consecutive amino acids sequences. Dragon *et al* disclose a peptide sequence that comprises 8 consecutive amino acids. The functional limitation of eliciting T-cell immune response does not read any patentable weight into the claims. These claims are drawn to a product and as such, the product taught by Dragon anticipates the product of the instant invention.

***Claim Rejections Maintained - 35 USC § 103***

9. The rejection of claims 7-10, 13, 19-21, 30-31, 34, 35 and now newly added claims 64 and 65 under 35 USC 103(a) as being obvious over Dragon *et al* in view of Prakken *et al* and Costa *et al* is maintained for the reasons of record. Applicant argues that neither Prakken *et al* nor Costa *et al* specifically disclose the use of the specifically claims peptide derived from hsp70 with either an adjuvant or vehicle. Applicant's arguments have been carefully considered but are not found persuasive. Dragon *et al* teaches a peptide that is identical to that discloses by the instant invention and further discloses that the peptide is derived from a heat shock protein. It would have been obvious to combine the teachings of Prakken *et al* and Costa *et al* with that of Dragon *et al* to make the instantly claimed invention because it was well known at the time of filing that the combination of adjuvants or vehicles to a composition would improve the ability of a composition to elicit an immune response. Furthermore, one of ordinary skill would have been motivated to do so because Dragon *et al*, Prakken *et al* and Costa *et al* all taught of heat shock proteins. Therefore, unless the instant invention described

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unexpected result in the combination of the heat shock proteins and adjuvants/vehicles, one of ordinary skill would have found the instant invention obvious over the prior art.

***New Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

10. Claims 11, 34, 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. With regard to claim 11 in the recitation of the term "chemical group", there are hundred if not thousands of such groups which would effectively do the same thing claimed. Because the claims have not specifically limited the type of group the metes and bounds of the term cannot be adequately determined.

12. With regard to claim 34 in the recitation of the phrase "at a distance from a tumor", it is unclear as to where this location of administration would be. Does the applicant intend the administration to take place in the foot if the tumor is located in the brain?

13. With regard to claim 35 in the recitation of the phrase "immediate vicinity near a tumor", this is seen as a relative, because everyone interprets the term "immediate" with different standards. As such the metes and bounds of the term cannot be determined.

***Conclusion***

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen  
Art Unit 1642  
April 4, 2003

  
ANTHONY G. CAPUTA  
SUPERVISOR  
TECHNICAL EXAMINER  
TECHNICAL EXAMINER 1000